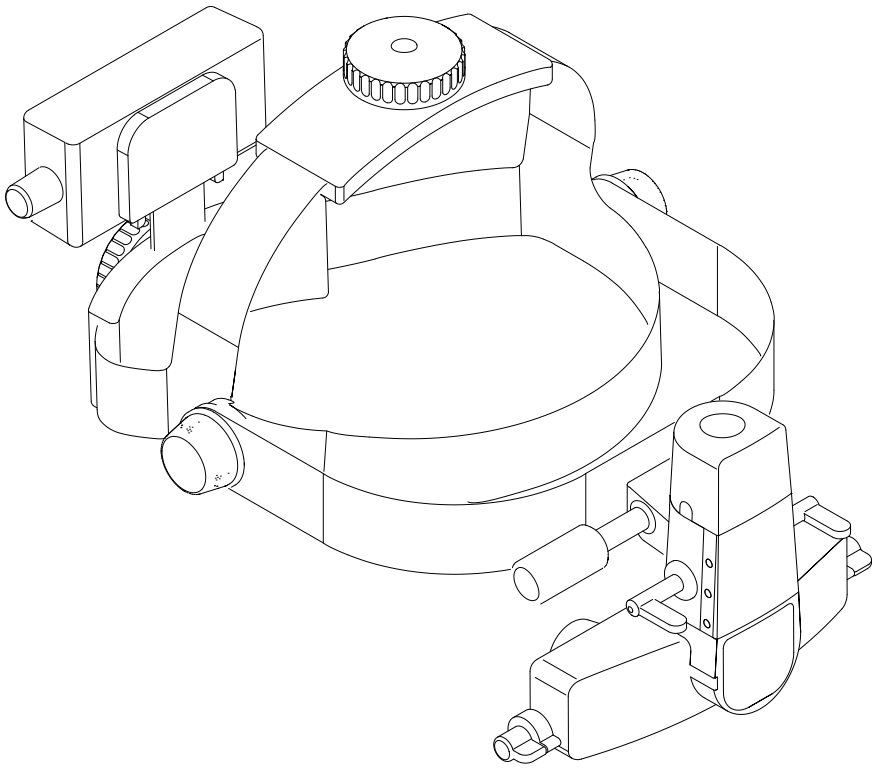
NEITZ
Made by Neitz for Your Medical Field

# Binocular Indirect Ophthalmoscope

# IO-α LED (Battery-powered Type)

# User's Manual



Thank you for purchasing the NEITZ Binocular Ophthalmoscope IO-α LED (Battery-powered Type). This is a battery-powered device to examine the inside and fundus of the eyes by illuminating with an LED bulb. The device is powered by the Battery Pack IO-BP3A which can be attached to the Headband or a belt and the like.

Please read this User's Manual carefully before use to avoid unexpected accidents and store it in a safe place for future reference.

VIEWLIGHT
POWERED BY INNOVATION

CE UKCA

TD11-13000002E-4

# Table of Contents

# 1 Important Information

For the U.S. Market;

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

## 1.1 Intended Use

The NEITZ Binocular Indirect Ophthalmoscope IO-α LED (Battery-powered Type) (hereinafter referred to as “IO-α”) is a battery powered medical device containing an LED bulb for illumination and viewing optics intended to examine the media (cornea, aqueous, lens and vitreous) and retina of the eye.
Do not use this device for any purpose other than its intended use.

## 1.2 Symbols

The following symbols are used on this manual and/or package to assist you in proper handling and use of the IO-α, and to warn and caution you of potential hazards to yourself and others.

| | |
|---|---|
| WARNING | Potentially hazardous situation which, if not avoided, could result in death or serious injury |
| CAUTION | Potentially hazardous situation which, if not avoided may result in minor or moderate injury or property damage |
| Prohibited | Prohibited actions (must not be performed) |
| Instruction | Required actions (must be performed) |
| | Consult User’s Manual for information on proper use |
| | Temperature limits (°C) for storage and transport |
| | Relative humidity limits (%) for storage and transport |
| | Atmospheric pressure limits (hPa) for storage and transport |
| | Fragile. Handle with care |
| | Keep dry |
| CE | Product complies with the European requirements for safety, health, environment and customer protection. |
| UK CA | Product complies with the applicable medical device regulations of the United Kingdom |
| | Product must not be disposed of with general household waste under the WEEE directive |

| | |
|---|---|
|  | Manufacturer’s name and address |
|  | Class II ME equipment |
|  | Alternating current (for the AC adapter) |
|  | Direct current (for the AC adapter) |
|  | For indoor use only |
|  | Certification symbols demonstrating product has passed the corresponding safety tests. |
|  | |
|  | |
|  | |
|  | |
|  | Lithium-ion rechargeable battery (must be recycled) |
|  | Barcode for traceability purposes and streamlined distribution (The barcode in the left is a sample.) |
|  | Symbol of a medical device |
|  | Serial number |
|  | Authorized representative in Europe |
|  | Symbol of the Administrative Measure on the Control of Pollution Caused by Electronic Information Products (China RoHS) |

## 1.3 Safety Information

For your safety, please comply with the following precautions.

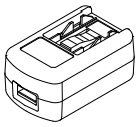
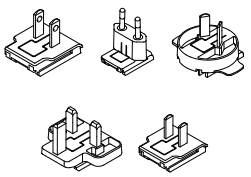
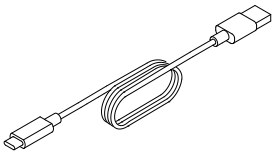
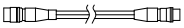
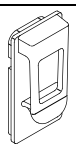
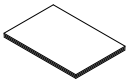
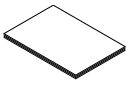
| ⚠WARNING | |
|---|---|
| Prohibited | Do not illuminate the patient's eye for more than 1 minute per eye and be sure to keep illumination at minimal intensity needed to view the fundus. |
| Prohibited | Do not connect the power cable to an outlet with too many other devices. Doing so may cause injury or fire. |
| Prohibited | Do not use damaged cables or cords. Doing so may cause electric shock, fire or device failure. |
| Prohibited | Do not use in oxygen rich environments, in the presence of propane, gasoline or other combustible gasses, or near dust and debris. Doing so may cause explosion. |
| Prohibited | Do not leave the illumination of for prolonged periods or cover the device during illumination. Doing so may cause the device to reach high temperatures. |
| Prohibited | Never touch liquid which may have leaked from the Battery Pack. In case of contact with the eye(s), flush with clean water without rubbing, and consult a physician immediately. If leaked liquid gets on skin or clothing, wash with clean water immediately. Failure to do so may result in serious injury, including loss of eyesight. |
| Prohibited | Do not short-circuit connectors or touch them with bare hands. Doing so may cause electric shock or device failure. |
| Prohibited | Do not attempt to disassemble or modify the device. Doing so may result in electric shock, fire or device failure. |
| Prohibited | Never remove the cover of the battery pack. Attempting to charge commercial batteries so may cause leakage of liquids, heat generation or rupturing during charging. |
| Prohibited | Do not touch the device with wet hands. Doing so may result in electric shock. |
| Instruction | In the event of ingress of water or other liquids, unplug from the power outlet immediately. Failure to do so may result in electric shock, fire or device failure. |
| Instruction | Unplug the power cable from the power outlet prior to cleaning. Failure to do so may result in electric shock |
| Instruction | Take care to only touch insulated parts when inserting the power plug into the power outlet. Failure to do so may cause electric shock or fire. |
| Instruction | Be sure not to loosen the Overband Fixation Knob too much. Doing so may free the knob and cause the Scope Unit to drop. |
| Instruction | Be sure to tighten the Overband Fixation Knob firmly after flipping the Overband up. Failure to do so may cause the Scope Unit to fall down. |

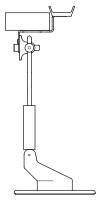
| ⚠CAUTION | |
|---|---|
| Prohibited | Do not sterilize the device. Doing so may cause device deformation or failure. |
| Prohibited | Do not install the device in places where it may be difficult to plug in/out to/from the power outlet or to switch power since the plug-out from the outlet is one of the separation methods between the device and the power supply |
| Prohibited | Do not use in excessively humid or saline environments, or places where the device may be sprayed with water. Doing so may result in electric shock or device failure. |
| Prohibited | Do not expose the device to direct sunlight or harmful radiation. Doing so may lead to unexpected heating and result in device failure. |
| Prohibited | Do not attempt to charge the device in temperatures exceeding 35 °C (95 °F). Doing so may prevent the device from charging or result in device failure. |
| Prohibited | Do not attempt to charge the device when wet. Doing so may cause excessive heating, fire or rupture. |
| Prohibited | Do not place heavy objects on, apply excessive tension to, or fold cables, cords and connectors. Doing so may result in damage and electric shock or fire. |
| Prohibited | Do not use paint thinners, cleaning agents or boiling water to clean the device. Doing so may cause deformation or device failure. |
| Prohibited | Do not immerse in cleaning detergents or rinse with water. Doing so may cause device failure. |
| Prohibited | Do not use accessories, spare parts, or options other than the ones specified in this manual. Use of foreign parts or accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation. |
| Prohibited | Use of the IO-α LED adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. |
| Prohibited | Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device. Otherwise, degradation of the illumination of the device could result. |
| Instruction | Unplug from the power outlet during long periods of disuse. Not doing so may cause fire or device failure. |
| Instruction | Allow the device to return to room temperature before unpacking. Not doing so may cause condensation and lead to device failure. |
| Instruction | Wear a cap or the like when equipping the IO-α LED. |
| Instruction | Make sure the illumination is turned off during transport or storage and only use the specified casing. Failure to do so may result in deformation, device failure or fire. |
| Instruction | When disconnecting cables, be sure to hold the plug. Never pull the cable. |

# 2 Checking Package Contents

## 2.1 Composition

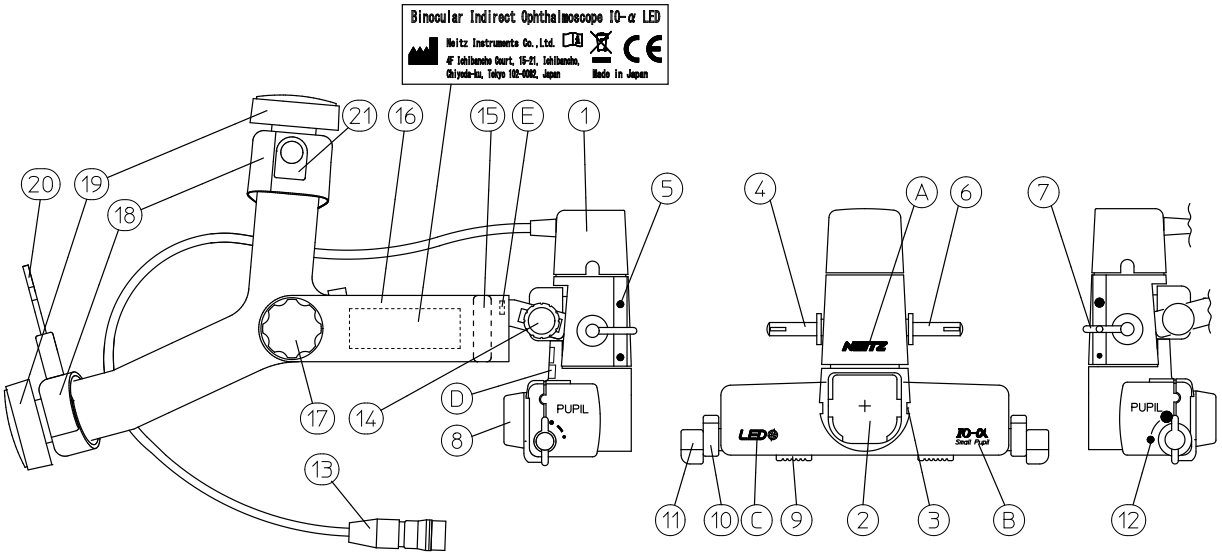
Make sure to match all items in the package with the components shown below and inspect each item for damage. Should any items be missing or damaged, do not use the IO-α and contact your local dealer immediately.

| Item \ Set Type | | Set 4 | Set 3 | Set 2 | Set 1 |
|---|---|---|---|---|---|
| IO-α main unit | See 2.2.1 | 1 | 1 | 1 | 1 |
| IO-BP3A | See 2.2.2 | 1 | 1 | 1 | - |
| AC Adapter set |   | 1 | 1 | 1 | - |
| USB cable (Type-C) |  | 1 | 1 | 1 | - |
| Extension cord (1 m) |  | 1 | 1 | 1 | 1 |
| Belt hook |  | 1 | 1 | 1 | - |
| Wiring ring |  | 1 | 1 | 1 | - |
| Teaching mirror |  | 1 | - | - | - |
| Detachment chart |  | 1 | - | - | - |
| User's manual |  | 1 | 1 | 1 | 1 |
| Carrying case |  | 1 | 1 | - | - |

| | | |
|---|---|---|
| Aspherical lens |  | Optional |
| Replacement bulb |  | Optional |
| IO stand |  | Optional |

## 2.2 Nomenclature

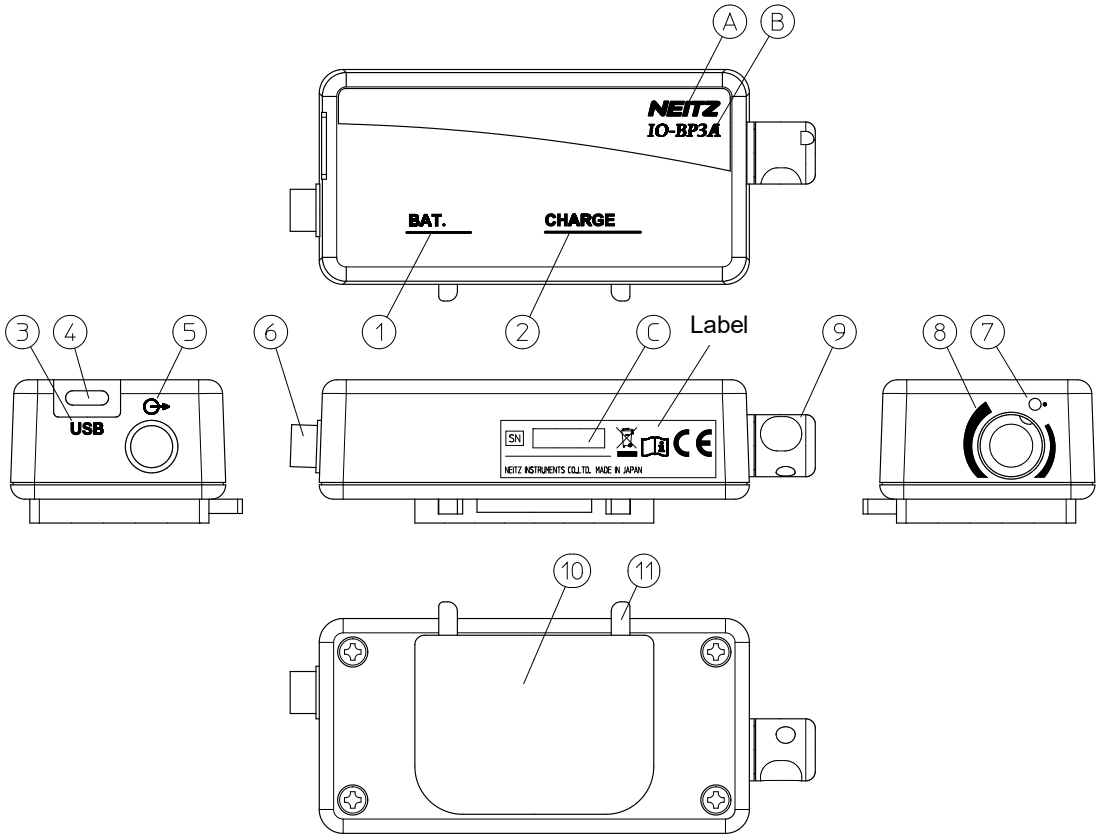
### 2.2.1 IO-α Main Unit




| | | |
|---|---|---|
| A | NEITZ | Manufacturer's logo |
| B | IO-α Small Pupil | Model logo |
| C | LED | Uses an LED bulb |
| D | SN ********* | Serial number of the Scope unit |
| E | SN ********* | Serial number of the Headband |
| 1 | Lamphouse | Holds the LED bulb |
| 2 | Front window | Outputs illumination |
| 3 | Teaching mirror slot | To insert the Teaching mirror |
| 4 | Filter selection lever | Allows for switching between "UV filter (white)", "Red-free filter (green)" and "Cobalt blue filter (blue)" |
| 5 | | Filter selection marker |
| 6 | Aperture selection lever | Switches the area of the illumination field |
| 7 | | Aperture selection marker |
| 8 | Eyepiece | A +2 D (diopter) lens is included |

| | | |
|---|---|---|
| 9 | PD adjuster | Adjusts the pupil distance (PD). The scale (54 mm to 74 mm) is indicated above the eyepiece |
| 10 | Illumination angle adjustment lever | Adjusts the illumination angle. Levers located on both sides of the scope unit are coupled and move in conjunction. |
| 11 | Observation angle adjustment lever | Adjusts the observation angle. Levers located on both sides of the scope unit are coupled and move in conjunction. |
| 12 |  | Graphic display of the approximate subject pupil size. |
| 13 | Lamp plug | Connects to the Lamp jack of the IO-BP3A |
| 14 | Scope unit fixation knob | Loosen to position the Scope unit |
| 15 | Headpad | Applied to the forehead to keep the scope unit in place |
| 16 | Overband | Holds the scope unit. Can be flipped up. |
| 17 | Overband fixation knob | Loosen to flip up the Overband. Tighten to keep the Ooverband in place |
| 18 | Headband cover(s) | Covers the adjustment mechanics of the Headband. For your safety, do not remove. |
| 19 | Headband size adjustment knob(s) | Turn clockwise to tighten the Headband. Turn counter-clockwise to loosen the Headband. |
| 20 | Battery pack fixation prong | Inserted into the Connector attachment to hold the battery pack |
| 21 | Cable fixation strap | Used to fix the Lamp cord to the Headband |

### 2.2.2 IO-BP3A




| | | |
|---|---|---|
| A | NEITZ | Manufacturer's logo |
| B | IO-BP3A | Model logo |
| C | SN ********* | Serial number of the IO-BP3A |
| 1 | BAT. | Battery indicator: The color of the LED in the right of this symbol shows the remaining battery amount. |
| 2 | CHARGE | Charge lamp: The color of the LED in the right of this symbol shows the remaining battery amount. |
| 3 | USB | Symbol showing the charging input port of the battery pack. |
| 4 | Charging input port | Charging input port of the battery pack with a protective cap. Accepts a USB Type-C connector. |
| 5 | ⊖→ | Symbol showing the output port (power supply) from the battery pack. |
| 6 | Output connector | Output connector from the battery pack. It supplies the power when connected to a suitable device. |
| 7 | ○• | Symbol for the ON / OFF position of the output from the battery pack. |
| 8 | ( ) | Symbol showing the output kevel from the battery pack. The thicker line shows the higher output level. |

| | | |
|---|---|---|
| 9 | Output switch | Turns on and off the output from the battery pack. By turning the switch, the output level will be adjusted steplessly. |
| 10 | Connector attachment | Used to attach the battery pack to the belt hook or the Headband of the suitable device. |
| 11 | Fixation release | Used to detach the battery pack from the Headband or belt hook. |

# 3 Operation

## 3.1 Preparation

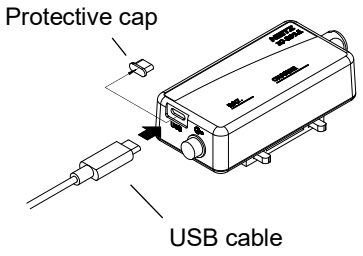
### 3.1.1 Charging the IO-BP3A

| | |
|---|---|
| ⚠ WARNING | Never remove the cover of the battery pack. Attempting to charge commercial batteries may cause leakage of liquids, heat generation or explosion during charging. |

(1) Attach one of the enclosed power plugs to the AC adapter (See “Attaching / detaching the power plug” below.) Several power plugs are enclosed. Choose the suitable one.

(2) Connect the AC adaptor and the Type-A terminal of the USB cable. Connect to the AC power outlet.

(3) Detach the protective cap from the charging input port of the battery pack and connect the Type-C terminal of the USB cable. The charge lamp will light orange and charging will start.




(4) Once the battery pack is fully charged, the charge lamp will light green. The Charging time is approximately 2 hours if the battery pack is fully discharged. Please note the battery pack cannot be used while charging.

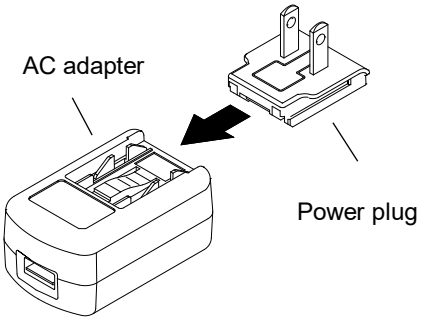
(5) Unplug the AC adapter power plug from the AC power outlet. Detach the USB cable from the battery pack.

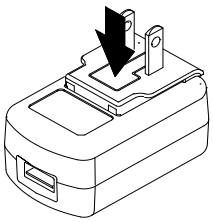
(6) To prevent ingress of foreign matters, cover the charging input port with the protective cap when the battery pack is not charged.

<Attaching / detaching the power plug>

How to attach:

Align the tabs of the AC adapter and grooves of the power plug. Slide the power plug in the direction of the arrow in the illustration to attach. It has a locking mechanism. Slide the power plug until you hear a clicking sound.



How to detach:

To release the lock, depress the power plug as the arrow in the illustration shows. Keep the power plug depressed and slide it to detach.

### 3.1.2 Attaching the IO-BP3A

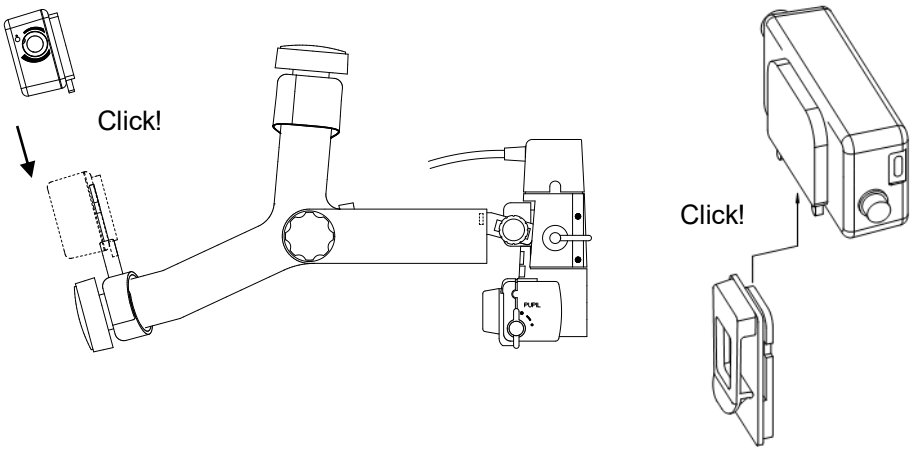
The IO-BP3A can be attached to either the Headband using the Headband hook or a belt or the like using the Belt hook.

**<Attaching to the Headband>**

Insert the Battery pack fixation prong on the Headband into the Connector attachment on the IO-BP3A
*Note: Be sure to insert the prong properly until the Fixation prong releases click.

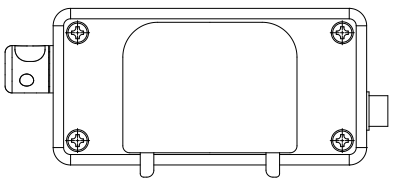
**<Attaching to the Belt hook>**

Insert the Battery pack fixation prong on the belt hook into the Connector attachment on the IO-BP3A
*Note: Be sure to insert the prong properly until the Fixation prong releases click.




**<Detaching the IO-BP3A>**

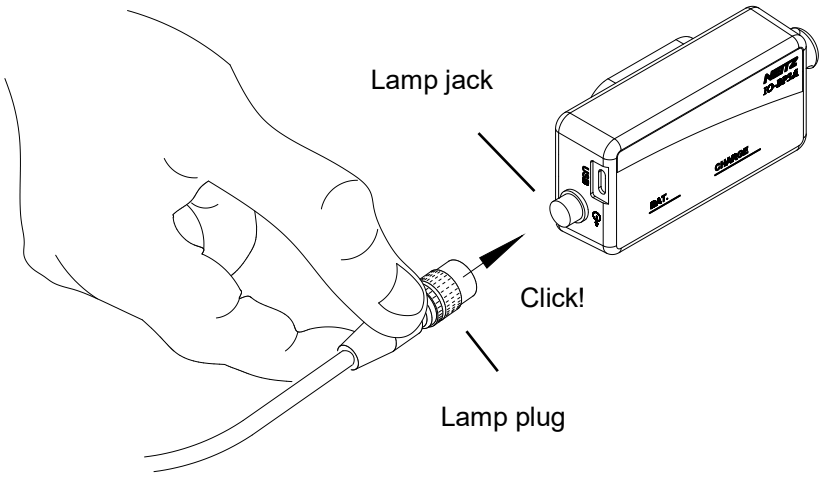
Squeeze the two Fixation prong releases inwards to release the Battery pack fixation prong from the Connector attachment.



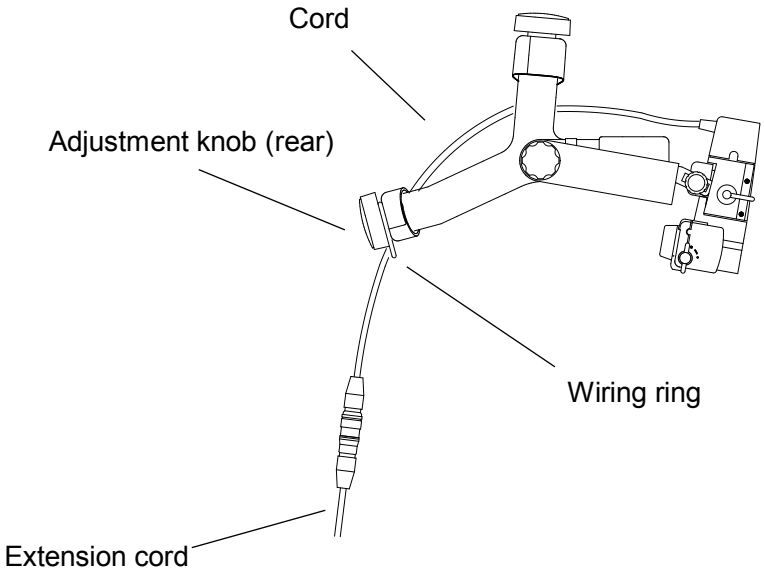
Squeeze inwards

### 3.1.3 Connecting the IO-BP3A to the Scope Unit

(1) Holding the **black rubber** portion, insert the Lamp plug into the Lamp jack. Make sure metal rings on the plug and jack interlock with a click (see Fig. 3.4).
*Note: The plug and jack interlock at a single configuration. Rotate the plug as needed to connect smoothly.

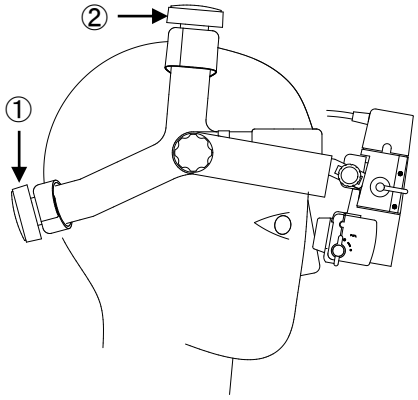



(2) When using the Belt hook, the Lamp cord attached to the Scope unit is not long enough to connect to the IO-BP3A. In this case, connect the Extension cord provided to the Lamp cord to accommodate. The Wiring ring can be used to keep the wiring from getting in your way.
(3) Gently pull the **metal ring** on the Lamp plug to disconnect from the IO-BP3A.
*Note: The cord will not disconnect by simply turning the metal ring.
(4) When using with IO-BP3A attached to your belt, connect the Extension cord between the Lamp plug and Lamp jack to extend the entire length. In this case, attach the Wiring ring to the rear of the Adjustment knob and pass the cord through the ring to reduce the burden due to the cord hanging down from your back.



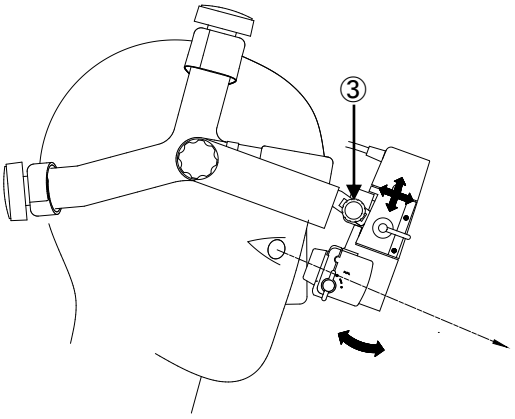
## 3.2 Operation

### 3.2.1 Wearing the IO-α LED



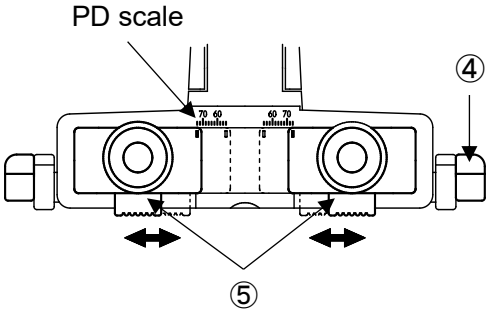

(1) Loosen the Headband by turning the Headband size adjustment knobs located at the top and rear of the Headband counter-clockwise and position the Headband so that it comes into contact with the forehead.
(2) Turn the rear Headband size adjustment knob (①) clockwise to tighten and keep the Headband in place. It is advised to lower the rear portion of the Headband to increase stability.
(3) Turn the top Headband size adjustment knob (②) clockwise to adjust the height.

### 3.2.2 Positioning the Scope Unit




(1) Loosen the Scope unit fixation knob (③) by turning counter-clockwise. Be sure to keep hold of the Scope unit while loosening, as the scope unit may suddenly tilt.
(2) Move the Scope unit and tighten the Scope unit fixation knob to fix in the position with the best view when observed through the eyepieces

### 3.2.3 PD Adjustment




(1) Turn the Observation angle adjustment lever (④) upward to fully spread the angle of observation.
(2) Focusing on an object (such as a thumb) approximately 400 mm from the Scope unit, move each eyepiece one at a time by sliding the PD adjuster (⑤) so that the object is centered in the field of view.

### 3.2.4 Illumination

(1) Turn the Illumination switch clockwise from the OFF position ( ) to turn the illumination on. Illumination intensity will increase as the switch is turned (a marking to indicate the intensity is shown as )
(2) Choose the desired field of illumination using the Aperture selection lever. The following diameters can be selected.

| Marker | Aperture | Diameter at 500 mm distance |
|---|---|---|
| ● | Large | 80 mm |
| ● | Medium | 50 mm |
| ● | Small | 19 mm |

(3) Rotate the Filter selection lever to choose between the 3 available filters below:

| Marker | Filter | Use |
|---|---|---|
| White | UV | Normal use. Filter will not alter the color tone |
| Green | Red-free | Blood will appear dark, facilitating recognition of blood vessels or hemorrhages. |
| Blue | Cobalt blue | Used in conjunction with fluorescein |

The color of the Battery lamp will change according to the amount of the remaining battery power as in the table below.

| Color | Condition of the battery pack and necessary actions |
|---|---|
| Green | Battery operational. Continue use |
| Orange | Little battery power remaining. Charge immediately |
| Unlit | Battery fully discharged. Charge immediately |

### 3.2.5 Examination

| | |
|---|---|
| ⚠ **WARNING** | Do not illuminate the patient's eye for more than 1 minute per eye and be sure to keep illumination at minimal intensity needed to view the fundus. |

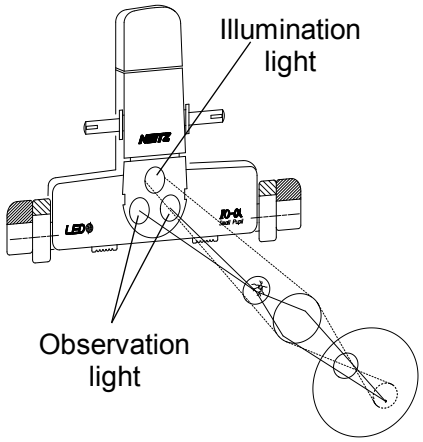
(1) Holding an aspherical lens in one hand, direct the illumination into the patient eye. It is recommended to place the unoccupied fingers of the hand holding the aspherical lens on the patient's face for stability.
(2) Bring the aspherical lens close to the patient eye and gradually move away from the eye until a clear image of the fundus is obtained.
*Note: The distance between the patient eye and aspherical lens is dependent on the optical power (diopter, 1 D = 1 / focal distance in meters) of the aspherical lens.

| Optical power | Description of the image |
|---|---|
| 14 D to 16 D | High magnification, bright image, narrow field of view |
| 20 D | Typically used in standard examinations |
| 28 D to 30 D | Low magnification, dim image, wide field of view |

The illumination system and observation system can be configured as follows to optimize examination

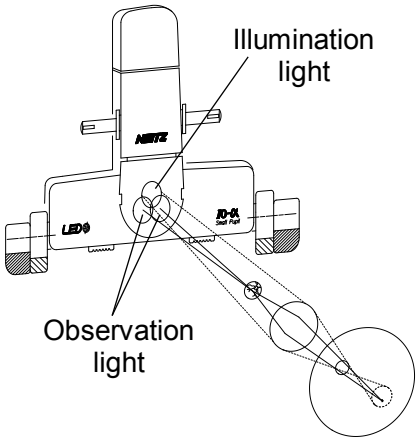
**<Examining large pupils>**

When examining the fundus through large pupils, raise both the Illumination angle adjustment lever and Observation angle adjustment lever. The illumination axis and observation axes are distanced, allowing for better stereoscopic vision with reduced glare.



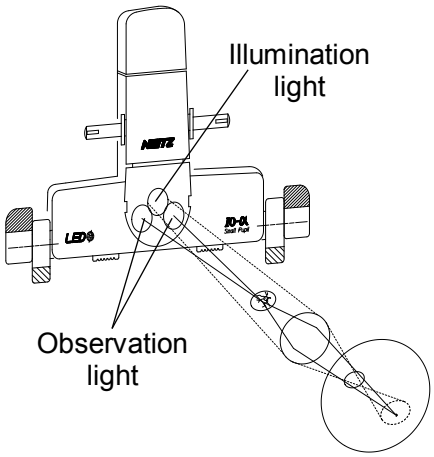
**<Examining small pupils>**

When examining the fundus through small pupils, lower both the Illumination angle adjustment lever and Observation angle adjustment lever. The illumination axis and observation axes come closer, allowing for easier concentration of light into the pupil.



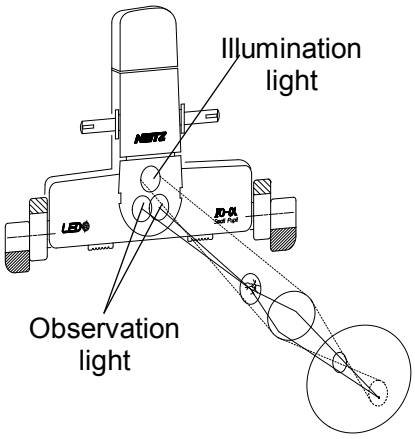

**<Examining horizontally elliptical pupils>**

When examining the fundus through horizontally elliptical pupils, lower the Illumination angle adjustment lever and raise the Observation angle adjustment lever. The illumination axis will come closer the observation axes while the observation axes remain apart.



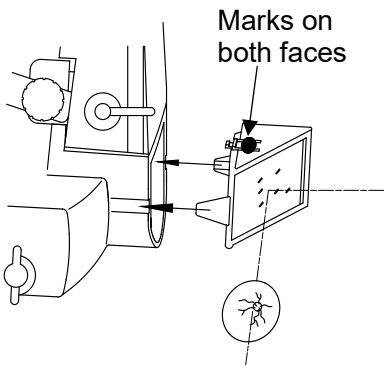

**<Examining vertically elliptical pupils>**

When examining the fundus through vertically elliptical pupils, raise the Illumination angle adjustment lever and lower the Observation angle adjustment lever. The illumination axis will remain apart while the observation axes come closer.




(3) Reflection off the cornea or front or back side of the aspherical lens may interfere during examination. In such cases, tilt the lens slightly to offset the reflection for better observation of the fundus.
(4) Use a scleral depressor to depress the eye for examination of the peripheral retina.

### 3.2.6 Using the Teaching Mirror




It is also possible to view the fundus image from the side by inserting the Teaching mirror into the Teaching mirror slot on the Scope unit.
The Teaching mirror may be attached to face either the left or right of the examiner.
When detaching the Teaching mirror from the Scope unit, depress the ● mark on both the upper and lower faces of the Teaching mirror and pull gently.

*Note: Do not attempt to detach the Teaching mirror forcefully as the Teaching mirror may break.

### 3.2.7 Turning Illumination Off

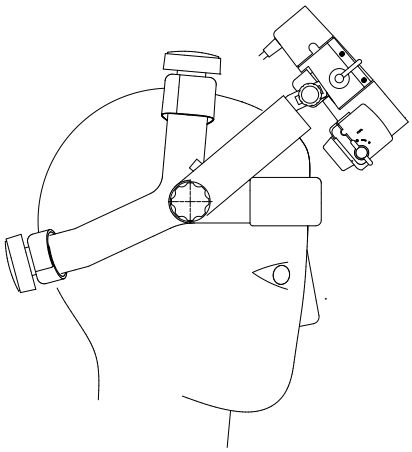
Turn the Illumination switch counter-clockwise to the OFF position ( ○ ) to turn the illumination off. Make sure to confirm the device is turned off by checking that the Battery lamp is unlit.

### 3.2.8 Flipping the Overband Up

| | |
|---|---|
| ⚠ **WARNING** | Be sure not to loosen the Overband fixation knob too much. Doing so may free the knob and cause the Scope unit to drop. |
| ⚠ **WARNING** | Be sure to tighten the Overband fixation knob firmly after flipping the Overband up. Failure to do so may cause the Scope unit to fall down. |

(1) Turn the Overband fixation knobs on both sides of the Headband counter-clockwise to loosen and flip the Headband up.

(2) Turn the Overband fixation knobs clockwise to tighten the knobs to keep the Scope unit fixed in a position where it is out of the line of sight.



# 4 Maintenance

| | |
|---|---|
| ⚠ WARNING | Unplug the power cable from the power outlet prior to cleaning. Failure to do so may result in electric shock |
| ⚠ WARNING | Do not short-circuit connectors or touch them with bare hands. Doing so may cause electric shock or device failure. |

## 4.1 Cleaning

### 4.1.1 Cleaning the Optics

If dust or other foreign matter should adhere to the optical glass, remove with an air blower or the like. If the foreign matter cannot be removed with an air blower, wipe gently using diluted neutral detergent and then wipe dry.

### 4.1.2 Cleaning the Headpad

When the Headpads become dirty, detach from the Headband and hand-wash with diluted neutral detergent and then dry completely.

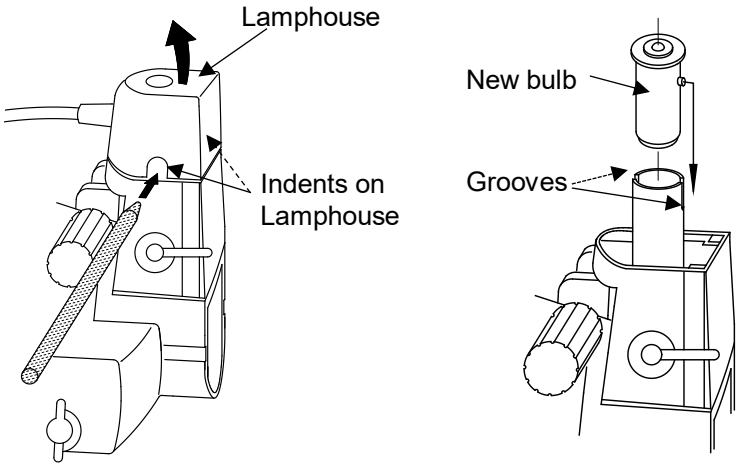
### 4.1.3 Cleaning Other Exterior Parts

Wipe the surface using a dry lint-free cloth or cloth moistened with diluted neutral detergent and then wipe dry. Use a cloth moistened with alcohol to disinfect.

## 4.2 Replacing the LED Bulb

As LED bulbs have a long lifetime, replacement is generally not necessary. However, should the need arise, follow the directions below to replace the LED bulb (see Fig 3.11).

(1) Confirm the illumination is turned OFF and disconnect the battery pack.
(2) Using a thin stick such as the tip of a pencil, press the indented tabs located on each side of the Lamphouse to remove the Lamphouse cover.
(3) Remove the old LED bulb and replace with a new one. When inserting the LED bulb, be sure to align the protrusion on the side of the bulb with either groove on the socket.
(4) Shut the cover of the Lamphouse until it shuts with a click
(5) Turn the illumination on for confirmation.



## 4.3 Replacing the IO-BP3A

| | |
|---|---|
| ⚠ WARNING | Never remove the cover of the battery pack. Attempting to charge commercial batteries so may cause leakage of liquids, heat generation or rupturing during charging. |

Rechargeable batteries degrade through repeated charging and discharging cycles. Degraded batteries experience shortened illumination times and eventually will cease to operate. If such events should occur, contact your local dealer to purchase a new Battery Pack.

## 4.4 Disposal

Dispose of the IO-α LED and its accessories (excluding the IO-BP3A) in accordance with your local regulations and/or environmental guidelines

The IO-BP3A incorporates rechargeable batteries which contain precious resources that can be reused. Recycle used rechargeable batteries in accordance with your local rules, regulations and guidelines.
The symbol shown to the right means “This product can be recycled” with text to indicate the material used, lithium-ion.

# 5 Troubleshooting

If you experience any problems using the IO-α, refer to the chart below for possible solutions. If the problem cannot be solved, stop using and immediately contact your local dealer or Neitz directly.

| Problem | Possible Cause | Solution |
|---|---|---|
| Illumination does not light | Incorrect cable connection | Correct the connection |
| | Battery empty | Charge the battery pack |
| | The USB cable is inserted | Remove the USB cable. |
| | LED bulb degraded | Replace with a new bulb in accordance with **4.2** |
| Illumination dark | Improper Illumination switch position | Adjust Illumination switch |
| | Insufficient charging | Charge the battery pack |
| | LED bulb degraded | Replace with a new bulb in accordance with **4.2** |
| Illumination flickers | Insufficient battery power | Charge the battery pack |
| Non-uniform illumination | Foreign matter is adhered to the front window | Clean in accordance with **4.1.1** |
| | Aperture selection lever or Filter selection lever is mispositioned | Move the lever(s) until you feel a click |
| Observation image blurry | Foreign matter is adhered to the eyepiece or observation system | Clean in accordance with **4.1.1** |
| | Foreign matter is adhered to the aspherical lens | Clean aspherical lens |
| Cannot charge | The USB cable is not fully plugged in | Plug in all the way |
| | The battery pack degraded | Replace the battery pack in accordance with **4.3** |
| Cannot charge despite AC adapter properly connected | Ambient temperature too high (a sensor is incorporated to detect high temperature) | Charge under the conditions specified in Section **6** |
| Reduced illumination time when fully charged | The battery pack degraded | Replace the battery pack in accordance with **4.3** |
| The battery pack becomes hot during charging | Heat occurring during charging is normal. The temperature of the battery pack may rise to temperatures which may feel slightly hot to the touch. | |
| Headband size loosens | Wear of the Headband size adjustment knob | Tighten the screw in the center of the knob. |
| Headband size fixation is loose | If the Headband size adjustment knob feels loose, tighten the screw in the center of the knob. | |

# 6 Specifications

## Product Specifications

| | | |
|---|---|---|
| ***Binocular Indirect Ophthalmoscope*** | | |
| Illumination Source | | Warm white LED |
| Filters | | UV, Red-free, Cobalt Blue |
| Illumination Field Diameter[*1] | | 19 mm / 50 mm / 80 mm |
| Maximum Illuminance[*1] | | Approximately 800 lx (when using the UV filter) |
| PD Adjustment Range | | 54 mm to 74 mm |
| Minimum Pupil Diameter | | 2 mm |
| Continuous Illumination Time[*2, 3] | | Approximately 5 hours at maximum intensity |
| Incorporated Rechargeable Battery | | Rechargeable lithium-ion batteries (3.7V) |
| Charging Time[*3] | | Approximately 2 hours |
| Dimensions | Scope unit[*4] | 164 mm x 111.5 mm x 58 mm<br>Approximately 480 g |
| | Headband circumference | Approximately 520 mm to 640 mm |
| | Battery pack[*5] | 90 mm x 45 mm x 30 mm<br>Approximately 90 g |
| ***AC Adaptor*** | | |
| Model | | SMI10-5-V-I38 |
| Power Input | Voltage | AC 100 V to 240 V |
| | Current | 0.3 A |
| | Frequency | 50 Hz to 60 Hz |
| Power Output | Voltage | DC 5 V |
| | Current | 2.0 A |

*1: measured at 500 mm distance
*2: The time until the illumination goes out when using new batteries.
*3: Reference values for new rechargeable batteries. The values may vary depending on the use conditions.
*4: excluding Headband
*5: excluding protrusions

## Classification

| | |
|---|---|
| Degree of protection against electric shock | Internally powered ME equipment |
| Applied parts | No applied parts |
| Degree of protection against harmful ingress of water or particulate matter | IP20 |
| Method(s) of sterilization | Do not sterilize |
| Suitability for use in an oxygen rich environment | Do not use in oxygen rich environments |
| Mode of operation | Continuous operation |
| ME system | When the AC adapter is connected, the charging mode will start and no illumination will turn up. |

## Safety Standards

| | |
|---|---|
| Electric Safety | IEC 60601-1: 2020 |
| Electromagnetic Disturbances | IEC 60601-1-2: 2020 |
| Ophthalmic Instruments | ISO 15004-1: 2020 |
| Light Hazard | ISO 15004-2: 2007 |

## Environmental Conditions

| | Use | Storage | Transport |
|---|---|---|---|
| Temperature | +10 °C to +35 °C<br>(50 °F to 90 °F) | -10 °C to +55 °C<br>(14 °F to 131 °F) | -10 °C to +55 °C<br>(14 °F to 131 °F) |
| Relative Humidity | 30 % to 90 %<br>(no condensation) | 10 % to 95 %<br>(no condensation) | 10 % to 95 %<br>(no condensation) |
| Atmospheric Pressure | 800 hPa to 1060 hPa | 500 hPa to 1060 hPa | 500 hPa to 1060 hPa |

# 7 Contact Information

If you have any questions or need technical support, contact your local dealer or Neitz located at the following address.

In the event of any serious incident that has occurred in relation to this product, please report the incident to the manufacturer, its authorized representative in Europe shown below and to the competent authority of your country of residence.

***[LOCAL DEALER]***

Neitz Instruments Co., Ltd.
4F Ichibancho Court, 15-21, Ichibancho, Chiyoda-ku
Tokyo 102-0082, Japan
Phone: +81-3-3237-0552 Fax: +81-3-3237-0554
E-mail: neitz-global@neitz.co.jp
URL: https://www.neitz.co.jp/en/

EC REP

***Medical Device Safety Service GmbH***
Schiffgraben 41, 30175 Hannover, Germany

UK Responsible Person

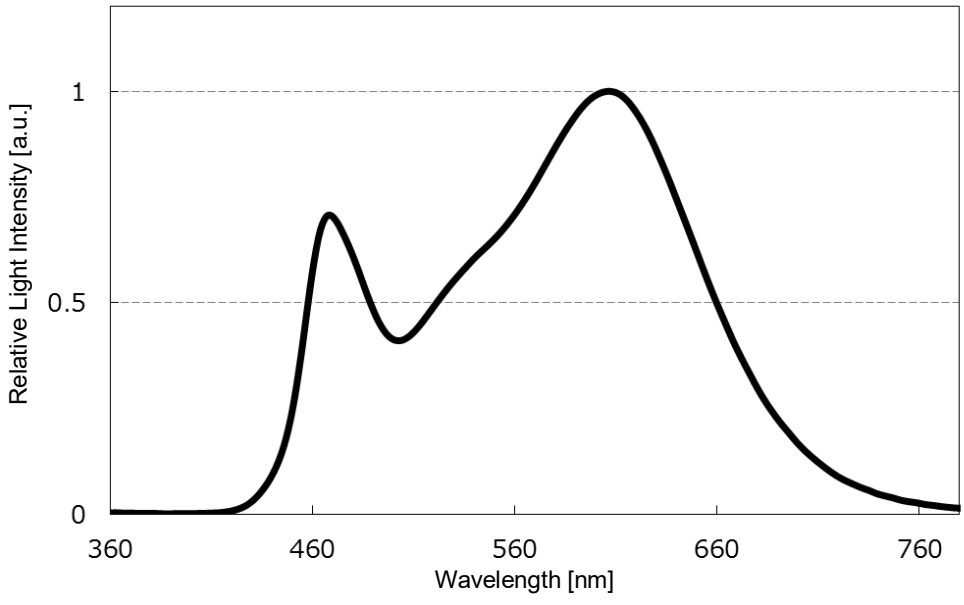
Qserve Group UK Ltd
282 Farnborough Road, Farnborough GU14 7NA
United Kingdom

# ANNEX A
## Protection from Optical Hazards

| | |
|---|---|
| ⚠CAUTION | **The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 7 minutes.** |

The figure below shows the relative optical output when the device is operated at maximum light intensity at the largest aperture. The figure represents wavelengths from 360 nm to 780 nm, as the LED light source does not emit radiation in the infrared or ultraviolet range.

*The results of evaluation according to ISO 15004-2 “Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection” indicates that the IO-α is classified to be Group 2 (and ophthalmic instrument for which a potential light hazard exists). Therefore, an indicator that shows that latent optical hazards could arise in relation to the ophthalmic instruments used by the operator is shown. However, this does not determine usage threshold values.
*The above-mentioned optical exposure time means the cumulative time over one day for one eye and this is inversely proportionate to the light intensity applied to the eye. Accordingly, if, for example, half of the maximum light intensity is used, the exposure time to reach latent optical hazard level is twice (approximately 14 minutes) that of when maximum intensity is used.
*Evaluations were taken using a 20 D aspherical lens with a diameter of approximately 49 mm. Results may vary depending on the actual condensing lens used during use of the device.



# ANNEX B
## Guidance of Electromagnetic Disturbances

The IO-α LED (battery-powered type) is a medical device and requires special precautions regarding EC. Refer to the following EMC information for appropriate installation and putting into service. Take care when using portable and mobile RF communications equipment in proximity of the IO-α LED (battery-powered type), as they can affect performance.

(1) Environments of intended use:
Professional healthcare facility environments and home healthcare environments

(2) Replaceable cables, transducers or accessories likely to affect compliance of the IO-α LED (battery-powered type) with the applied EMC Standard:
U2C-AC20NBK

(3) Applied EMC Standard: IEC 60601-1-2: 2020
Applicable port(s): Enclosure port, Input AC power port

| **Electromagnetic Emissions** | | |
|---|---|---|
| **Phenomenon** | **Applied / Conforming Standard** | **Emission Test Levels** |
| Conducted and radiated RF emissions | CISPR 11 | Class B Group 1 |

| **Electromagnetic Immunity** | | |
|---|---|---|
| **Phenomenon** | **Applied Standard** | **Conforming Test Levels** |
| Electrostatic discharge | IEC 61000-4-2 | ± 8 kV contact<br>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air |
| Radiated RF EM fields / Proximity fields from RF wireless communications equipment | IEC 61000-4-3 | 10 V/m, 80 MHz – 2.7 GHz,<br>80 % AM at 1 kHz<br>30 V/m, 300 MHz – 500 MHz,<br>80 % AM at 1 kHz<br>385 MHz – 5785 MHz, 9 – 28 V/m,<br>Pulse modulation 18/217 Hz / FM modulation ±5 KHz Deviation 1 KHz sine |
| Electrical fast transients / bursts | IEC 61000-4-4 | Input AC power: ± 2 kV (100 kHz) |
| Surges | IEC 61000-4-5 | Line-to-line: ± 0.5 kV, ± 1 kV |
| Conducted disturbances induced by RF fields | IEC 61000-4-6 | 0.15 MHz – 80 MHz: 3V<br>6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz<br>80 % AM at 1 kHz |
| Rated power frequency magnetic fields | IEC 61000-4-8 | 30 A/m<br>50 Hz or 60 Hz |

| Electromagnetic Immunity | | |
|---|---|---|
| **Phenomenon** | **Applied Standard** | **Conforming Test Levels** |
| Voltage dips and short interruptions | IEC 61000-4-11 | 0 % $U_T$: 0.5 cycles<br>at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°<br>0 % $U_T$: 1 cycle<br>70 % $U_T$: 25/30 cycles<br>single phase: at 0°<br>0 % $U_T$: 250/300 cycles (50/60 Hz) |
| Note: $U_T$ is the AC mains voltage prior to application of the test level | | |

(4) Essential Performance of the IO-α LED

| No. | Essential Performance | Outcome if essential performance is lost or degraded |
|---|---|---|
| 1 | Continuous steady illumination | Flickering illumination |

(5) For electromagnetic disturbances, the device has no necessary matter to keep the basic safety and maintain the essential performance during its expected lifetime.

***Notes:***

***Notes:***

***Notes:***

**Manufactured by**
***NEITZ INSTRUMENTS CO., LTD.***
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**Distributed by**

As part of our policy of continued product improvement, we reserve the right to alter and/or amend specifications at any time without prior notice.

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